

**Airline and Vessel and Traveler Information Collection  
(42 CFR Part 71)  
(OMB Control No. 0920-XXXX)  
Request for New Information Collection  
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**Airline and Vessel and Traveler Information Collection**  
**(42 CFR Part 71)**  
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- The goal of this information collection is to ensure that, consistent with the terms of the accompanying Final Rule, and the authorities in the Public Health Service Act and in Code of Federal Regulations (CFR), CDC can collect conveyance, passenger and crew member manifest information (aka manifests) in the event an individual with a confirmed or suspected case of a communicable disease is known to have traveled on an airline or vessel while infectious or potentially infectious and presented a risk of spread to other passengers or crew, and so that CDC can initiate the process of contact tracing or provision of other public health follow up to prevent further disease spread.
- The intended use of the information is to enable CDC to provide contact information to state and local health departments, so they can contact travelers in a timely manner to provide them with a notification that they may have been exposed to a communicable disease and to provide follow-up health information and any recommended interventions. In limited circumstances CDC may contact travelers directly.
- There are no statistical sampling or research design methods being used. CDC makes a determination of whether or not to collect manifest information depending on the risk of communicable disease spread during and after travel.
- There is no subpopulation being studied. The universe of respondents is any airline or maritime company operating an airline or vessel aboard which an infectious or potentially infectious individual is confirmed to have traveled.
- Data will be analyzed to ensure that timely responses from

**A. Justification**

**1. Circumstances Making the Collection of Information Necessary**

This information collection accompanies a Final Rule affecting 42 CFR parts 70 and 71. These parts outline CDC's regulatory and public health mission, and part 71 specifies CDC's authority related to the collection of passenger and crew manifest information from airlines and vessels when there has been a confirmed or suspected case of communicable disease aboard a flight or maritime voyage that puts other travelers at risk. This information collection request focuses on 42 CFR part 71 and pertains to flights arriving into the United States from international points of origin.

The rapid speed and tremendous volume of international and transcontinental travel, commerce, and human migration enable microbial threats to disperse worldwide in 24

hours - less time than the incubation period of most communicable diseases. These and other forces intrinsic to modern technology and ways of life favor the emergence of new communicable diseases and the reemergence or increased severity of known communicable diseases.

Stopping a communicable disease outbreak – whether it is naturally occurring or intentionally caused – requires the use of the most rapid and effective public health tools available. Basic public health practices, such as collaborating with airlines in the identification and notification of potentially exposed contacts, are critical tools in the fight against the introduction, transmission, and spread of communicable disease in the United States.

The collection of timely, accurate, and complete conveyance and traveler information enables Quarantine Officers in CDC’s Division of Global Migration and Quarantine (DGMQ) to notify state and local health departments in order for them to make contact with individuals who may have been exposed to a communicable disease during travel and identify appropriate next steps.

Section 361 of the Public Health Service Act (42 USC 264) (Attachment 1A) authorizes the Secretary of the Department of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States, or from one State or possession into any other State or possession. Regulations that implement federal quarantine authority are currently promulgated in 42 CFR parts 70 (Attachment 1B) and 71 (Attachment 1C). Part 71 contains regulations to prevent the introduction, transmission, and spread of communicable diseases into the states and possessions of the United States, while part 70 contains regulations to prevent the introduction, transmission, or spread of communicable diseases from one state into another.

Specific provisions in the Final Rule at 42 CFR 71.4 and 42 CFR 71.5 clarify that CDC, as the federal public health authority, has explicit authority to require that airlines and ships provide to CDC, within 24 hours, specific PII and contact information on travelers to prevent the introduction and spread of disease into the United States and between the states and possessions. CDC currently carries out these same activities under broad general authority provided by 42 CFR 71.32 for both international air and maritime arrivals. CDC anticipates that, while this is not a new practice, the listing of specific data elements in specific regulatory provisions will improve the submission of more timely, accurate, and complete traveler contact information by air and maritime companies

The description of the information collection processes following below is aligned with current practices.

## **2. Purpose and Use of Information Collection**

Control of disease transmission within the United States is largely considered to be the province of State and local health authorities, with Federal assistance being sought by those authorities on a cooperative basis, without application of Federal regulations. The

regulations at 42 CFR 71 were developed to facilitate Federal action in the event of ill travelers or deaths onboard arriving international flights.

Passenger and crewmember manifests contain certain information for travelers on airlines and vessels, and are generally collected from airlines and vessels when a disease is confirmed after travel has been completed. Manifests include locating and contact information, as well as information concerning where passengers sat while aboard an airline or their location (e.g. cabin numbers) and activities aboard a vessel. The specific list of data elements included in the rulemaking is:

- Full name (last, first, and, if available, middle or others);
- Date of birth;
- Sex;
- Country of residence;
- If a passport is required; passport number, passport country of issuance, and passport expiration date;
- If a travel document, other than a passport is required, travel document type, travel document number, travel document country of issuance and travel document expiration date;
- Address while in the United States (number and street, city, state, and zip code), except that U.S. citizens and lawful permanent residents will provide address of permanent residence in the U.S.(number and street, city, state, and zip code; as applicable);
- Primary contact phone number to include country code;
- Secondary contact phone number to include country code;
- Email address;
- Airline name;
- Flight number;
- City of departure;
- Departure date and time;
- City of arrival;
- Arrival date and time; and
- Seat number for all passengers

CDC also requests seat configuration for the requested contact area (example: AB/aisle/CDE/aisle/FG, bulkhead in front of row 9).

In the event that there is a confirmed case of communicable disease aboard an airline or vessel, CDC collects manifest information for those passengers or crew at risk for exposure. This specific manifest information collection differs depending on the communicable disease that is confirmed during air or maritime travel. CDC then uses this passenger and crew manifest information to coordinate with state and local health departments so they can follow-up with residents who live or are currently located in their jurisdiction. In the vast majority of cases, the manifests are issued for air travel and state and local health departments are responsible for the contact investigations; airlines and vessels may take responsibility for follow-up of crew members. In rare cases, CDC may use the manifest data to perform the contact investigation directly. In all cases, CDC works with state and local health departments to ensure individuals are contacted and provided appropriate public health follow-up.

### **3. Use of Improved Information Technology and Burden Reduction**

CDC sends the manifest orders via email or fax. Some airlines have specific forms that they require CDC to complete and submit along with the order; for example, the International Air Transport Association (IATA) [Request Form for Passenger Contact Tracing](#). All submission of manifest information is accomplished in a secure manner, either via email or fax.

### **4. Efforts to Identify Duplication and Use of Similar Information**

CDC has the regulatory authority for public health activities involving responses to illness and death aboard international and interstate flights and maritime voyages. This includes responding to a report of an ill traveler or death of a traveler on a conveyance, or, when notified by the Department of Homeland Security (DHS) personnel at a port of entry. As a result, CDC is the only agency collecting manifest information from airlines and vessels for the purposes of communicable disease response. CDC works in collaboration with its international, federal, state, and local partners at ports of entry to ensure all orders for manifests are performed in a coordinated manner and that the collection is limited to only the information needed to perform essential public health functions. CDC also relies on data collection systems managed by DHS that are already collecting several of the data elements from the airlines and maritime companies. CDC is not asking for the airlines and maritime companies to collect any additional information than we currently collect using the manifest orders, only that what is collected and what aligns with the listed data elements in 71.4 and 71.5 be provided with 24 hours of CDC's request.

### **5. Impact on Small Businesses or Other Small Entities**

While some aviation, maritime, and other travel companies may be considered small businesses, CDC anticipates that the vast majority of the burden rests with larger passenger airline and cruise line companies. In all cases, the manifest collection has been designed to include the absolute minimum in order to minimize the burden to the airlines and vessels.

### **6. Consequences of Collecting the Information Less Frequently**

Information will only be collected when a death or suspected communicable disease is confirmed to be a public health risk to travelers on an airline and in the receiving communities. Further reduction of required reporting would prevent CDC from meeting its statutory and public health mission, thereby endangering the public's health.

### **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This request fully complies with the regulation 5 CFR 1320.5. Passenger and crew manifest information must be collected on an as needed basis, determined by the public health risk, if it is to be used to prevent the spread of disease into or within the United States. There is no format specified as part of this information collection as long as CDC receives from the airlines and vessels the pieces of data required to make contact with individuals.

## **8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

A. A 60-day Federal Register Notice (Attachment 2) was published in the Federal Register on August 15, 2016, Vol. 81, No. 157, p. 54230. CDC received public comments from individuals and industry on the collection of passenger contact information. CDC has responded to these comments in the accompanying Final Rule.

B. CDC communicates frequently with airlines and vessels when illness or death is confirmed to have occurred during a flight or maritime voyage. To attempt to streamline the process and work with airlines' policies and procedures, CDC routinely complies with certain airlines' requests to complete their proprietary data request form for each manifest. CDC is also considering the adoption of the International Air Transport Association data request form. CDC makes every attempt to ensure that the collection of manifest information is not an undue burden on the respondents. No specific consultations regarding manifest requests have occurred with maritime vessel operators, because vessel manifest requests are very rare.

Prior to publication of the accompanying Final Rule, CDC had discussions with the DHS on the codification of these current practices into specific regulatory provisions. DHS had no objections.

## **9. Explanation of Any Payment or Gift to Respondents**

No payment is made to any respondent.

## **10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

This information collection request has been reviewed by the CDC National Center for Emerging and Zoonotic Diseases (NCEZID). NCEZID has determined that the Privacy Act does apply to this information collection request. The applicable System of Records Notice is 09-20-0171.

Information submitted by the airlines and vessel is entered into a secure electronic database called the Quarantine Activity Reporting System (QARS). It is stored here for analysis, for processing to complete the passenger information data set, for swift dissemination to the state and local health departments through a secure CDC system called Epi-X (Epidemic Information Exchange), and for later retrieval if necessary.

Electronic media will be protected by adequate physical, administrative, and procedural safeguards to ensure the security of the data. Access is restricted to agency employees with a bona fide “need to know” in order to carry out the duties of their positions or to accomplish the purposes for which the data were collected. Source data sets, printouts and thumb drives are safeguarded by storing them in locked cabinets in locked offices when not in use.

Further information concerning the protection of privacy can be found in the attached Privacy Impact Assessment (Attachment 3).

## **11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

### **IRB Approval**

The protocols and tools used to conduct this information collection request have been reviewed and approved by NCEZID’s Human Subjects Advisor, who determined that this data collection does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required (Attachment 4 CDC Nonresearch Determination Letter).

Manifests are ordered by CDC and submitted to CDC by the airline or vessel to prevent the spread of communicable diseases from foreign countries into the United States and from one State or possession into any other State or possession. Obtaining personally identifiable information, such as name, address, contact information, and travel document number, may be necessary during follow-up of potentially exposed passengers and crewmembers onboard. The information is only collected when it is required, and the information included in the manifest order is the minimum necessary to meet statutory and public health obligations.

## **12. Estimates of Annualized Burden Hours and Costs**

A. Manifest orders are sent to airlines, and very rarely vessel operators (less than 10 times a year), and are most often the result of confirmed cases of infectious tuberculosis in individuals who traveled on an airline. However, CDC also collects manifests for other communicable diseases, e.g. pertussis, measles, and meningococcal disease. Because there are fewer communicable disease incidents when manifests are ordered for these other communicable diseases, CDC has developed two template letters to facilitate the collection of manifest information on international flights to the United States. The templates are as follows:

- International TB Manifest Template Order (Attachment 5)
- International Non-TB Manifest Template Order (Attachment 6)

CDC staff populate the order templates and an accompanying cover letter (Attachment 7) and/or other airline requirement (e.g. International Air Transport Association Request Form for Passenger Contact Tracing (Attachment 8)) with information that is available when an individual is confirmed to have a communicable disease that was infectious during travel. This information includes the nature of the communicable disease, flight itinerary information, the number and position of seats that should be submitted to CDC



as manifest information, data elements requested for each traveler, and when the manifest information should be submitted to CDC. Airlines then follow their own protocols for reviewing the order and processing the manifest information to submit to CDC. CDC has no visibility on these processes; therefore, CDC is estimating the amount of time necessary to review the manifest order, look through their data systems, and provide the passenger manifest data to CDC. CDC estimates this activity could require between 4 and 8 hours per manifest search. We are including an average of 6 hours in this information collection request. We are including a 50/50 time split for airline respondent type, with equal time apportioned to an Airline Medical Officer or Equivalent and a Computer and Information Systems Manager. We are including equal time for each type of airline company respondent as CDC does not have knowledge of internal airline data submission practices.

In the event that advanced notice to the airline is needed in extremely pressing cases of infectious diseases, an informal manifest request template (Attachment 9) is sent, which is followed as soon as possible with the formal order. If the airline responds to the informal request prior to the formal order, CDC will follow up with a formal receipt of manifest letter (Attachment 10) for the airline’s records.

Reviewing data in QARS related to manifest orders, CDC estimates that there are approximately 96 international manifest orders sent to airlines each year. We are providing an upper bound estimate for this information collection request to ensure that the burden is sufficient to cover routine and response oriented manifest collections.

Although the justification and need for vessel manifest orders is outlined above, CDC sends less than 10 manifest requests to vessel operators per year, so they are not accounted for in the burden table.

The total anticipated respondent burden associated with this information collection request is

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Airline Medical Officer or Equivalent/ Computer and Information Systems Manager	International TB Manifest Template	67	1	360/60	402

Airline Medical Officer or Equivalent/ Computer and Information Systems Manager	International Non-TB Manifest Template.	29	1	360/60	174
<b>Total</b>					576

B. The cost to respondents was calculated using the May 2014 National Occupational Employment and Wage Estimates United States data from the Bureau of Labor Statistics ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)). The total estimated respondent cost is \$35,539.20.

#### Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Airline Medical Officer or Equivalent/ Computer and Information Systems Manager	International TB Manifest Template	402	\$61.70	\$24,803.40
Airline Medical Officer or Equivalent/ Computer and Information Systems Manager	International Non-TB Manifest Template.	174	\$61.70	\$10,735.80
<b>Total</b>				\$35,539.20

Respondents for this information collection include Airline /Maritime Medical Officer or Computer and Information Systems Manager. The mean hourly wages for this category of respondent was calculated using occupation and wage statistics from the Bureau of Labor Statistics (BLS).

- For Airline Medical Officer or Equivalent, we developed a weighted average of 29-1171 Nurse Practitioners - \$47.11 per hour (80%) and 29-1062 Family and General Practitioners - \$89.58 per hour (20%). This equals \$55.60 per hour.
- For Computer and Information Systems Manager we used 11-3021 Computer and Information Systems Managers, with a mean hourly wage of \$67.79
  - o The average wage used is  $(\$55.60 + \$67.79) / 2 = \$61.70$

### 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

None

## 14. Annualized Cost to the Government

For each manifest order several DGMQ staff are involved in developing the template, sending it to the airline, and reviewing and processing the manifest after it has been received at CDC. In addition to staff time, the database QARS is used to organize the manifest data, and document and provide context for the manifest order.

CDC estimates the yearly cost for this information collection request as a function of the staff time required to send, receive, process and distribute the passenger manifest information, the pay level of the average CDC staff member performing these tasks, and the IT costs associated with the QARS system.

### Staff hours

The total staff hours used for this estimation correlate to the total hours required of CDC headquarters and Quarantine Station field staff to develop the manifest order template and cover letter and send the order to the airlines, to enter the received manifest information into QARS, to compare the received manifest information with other sources of passenger information (i.e. DHS), and then to compile the manifest information and distribute it to the state health departments with jurisdiction over where the at-risk travelers reside. The breakdown in the following table is an outline of the number of hours required for each manifest order. The total is then multiplied by 125 to provide the total cost per year for this activity.

For average hourly wage, depending on the Quarantine Station with jurisdiction for where the flight arrived with the confirmed death or illness, different staff will complete the Informal Manifest Request, and Formal Manifest Order and Cover Letter, and send these documents to airline. Generally, the staff will either be a GS9 or GS13 depending on the staff compliment at the station, with GS9s being more likely to complete these tasks. Therefore we have used a weighted average of 60% for GS9 and 40% for GS13. OPM wages used are from the Atlanta locality and are set at step one.

	Time in hours required perform activity in manifest collection	GS Level or Equivalent	Average hourly wage of staff reviewing data	Total Estimated Yearly Cost
Complete Informal Manifest Request	.5	9 or 13	\$31.25	\$15.63
Complete Formal Manifest Order and Cover Letter and send to airline	1	9 or 13	\$31.25	\$31.25
After receipt of initial manifest data, creation of	1.5	12	\$35.14	\$52.71

NTC spreadsheet				
Submission of NTC data request for additional identifiers via HSIN	.25	12	\$35.14	\$8.79
Fulfillment of NTC data request	4	13	\$41.79	\$167.16
Upon receipt of NTC data, clean/verify additional data in spreadsheet	1.5	12	\$35.14	\$52.71
Compile the manifest information and distribute to states via Epi-X	.75	12	\$35.14	\$26.36
<b>Total</b>	9.5			\$354.61

The total staff costs dedicated to the approximately 96 manifest orders per year is approximately \$34,042 (rounded) per year. This is assessed by multiplying the 96 manifest orders by the total cost of processing one manifest, which is \$354.61.

There are also system and personnel costs associated with the use, development, and maintenance of QARS. These costs include the IT costs and associated staffing costs. The QARS related costs dedicated only to manifest data entry and processing cannot be separated from the total QARS system costs; therefore, the total QARS costs are presented here. These costs are as follows:

QARS System Costs	\$199,669
Staff Costs (Atlanta locality adjustment): 1xGS-12 and 1xGS-9(75%)	\$111,281
<b>Total</b>	<b>\$310,950</b>

The total costs associated with the staff development of the manifest order and processing of the received manifest, as well as QARS associated IT and staff costs, are approximately \$344,992.

## 15. Explanation of Program Changes or Adjustments

This is a new information collection request for a collection accompanying a Final Rule.

## 16. Plans for Tabulation and Publication and Project Time Schedule

Data are not collected for statistical purposes, but only to meet the regulatory and public health mandate as outlined in 42 CFR Part 70 and 71.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

No exemption is requested.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

## **Attachments**

Attachment 1A: Section 361 of the Public Health Service Act (42 USC 264)

Attachment 1B: 42 CFR Part 71

Attachment 1C: 42 CFR Part 70

Attachment 2: Attachment 2: 60 day Federal Register Notice

Attachment 2B: Public comment

Attachment 3: Privacy Impact Assessment

Attachment 4: CDC Non-research determination

Attachment 5: International TB Manifest Template Order

Attachment 6: International Non-TB Manifest Template Order

Attachment 7: Order Cover Letter

Attachment 8: IATA Passenger Manifest Information Request Form Contact Tracing

Attachment 9: Informal manifest request template

Attachment 10: Receipt of manifest letter